

REMARKS

This Amendment is submitted in response to the Office Action dated May 22, 2007. In the Office Action, the Patent Office rejected Claims 1-123 under 35 U.S.C. §101 for being directed to non-statutory subject matter. Furthermore, Claim 48 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Still further, the Patent Office objected to Claim 30 because of formalities.

Still further, the Patent Office rejected Claims 21, 47, 49, 52-55 and 112 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,898,535 to *Bergersen* (hereinafter "the '535 patent"). Moreover, the Patent Office rejected Claims 50 and 51 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of U.S. Patent No. 5,876,199 to *Bergersen* (hereinafter "the '199 patent"); and rejected Claim 52 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of U.S. Patent No. 5,645,420 to *Bergersen* (hereinafter "the '420 patent").

By the present Amendment, Applicant amended Claims 1, 8, 14, 21, 30, 40, 47, 48, 56, 65, 78, 87, 92, 103, 112, 117, 118, 120, 122 and 123. Applicant submits that the amendments to the claims overcome the objections and rejections by the Patent Office and place the application in condition for allowance. Notice to that effect is respectfully requested.

Applicant notes with appreciation that the Patent Office, in a telephone conversation between Applicant's representative Aaron

Morrow and Examiner O'Connor on June 27, 2007, Examiner O'Connor indicated that Claims 1-20, 22-29, 31-46, 56-111 and 113-123 would be allowable if the rejection under 35 U.S.C. §101 was overcome. Further, Examiner O'Connor indicated that amendment of the claims to state that the device is "designed to be worn in the mouth of a user" would overcome the rejection under 35 U.S.C. §101. Accordingly, Applicant amended Claims 1, 8, 14, 21, 30, 40, 47, 56, 65, 78, 87, 92, 103, 112, 117, 118, 120, 122 and 123 to state that the device is "designed to be worn in the mouth of a user" so that these independent claims do not positively recite part of a human.

With respect to the objection to Claim 30 because of informalities, Applicant amended "prevent" to "prevented" as suggested by the Examiner. Therefore, the objection has been overcome.

With respect to the rejection of Claim 48 under 35 U.S.C. §112, first paragraph, Applicant respectfully submits that the rejection has been overcome by the amendment to Claim 48. More specifically, in Claim 48, Applicant amended the claim to a "pivot that connects the upper portion of the hinge to the lower portion of the hinge". Therefore, the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Notice to that effect is respectfully requested.

With respect to the rejection of Claims 21, 47, 49, 52-55 and 112 under 35 U.S.C. §102(b) as being anticipated by the '535 patent, Applicant submits that the rejection has been overcome in view of the foregoing amendments to the claims and the remarks that follow.

Independent Claim 21, as amended, requires that the hinge is removed and re-inserted into the first slot and the second slot to reversibly detach and re-attach the upper base to the lower base. Independent Claim 47, as amended, requires that the hinge has an upper portion and a lower portion wherein the upper base has a first slot and a second slot wherein the upper portion of the hinge is removed and re-inserted into the first slot and lower portion of the hinge is removed and re-inserted into the second slot to reversibly detach and re-attach the upper base to the lower base. Independent Claim 112, as amended, requires that returning the hinge to the upper slot in the upper base and the lower slot in the lower base re-attaches the upper base to the lower base.

In contrast, the '535 patent merely teaches a removable orthodontic appliance with a means for retaining the appliance within the user's mouth. The appliance has an upper tooth receiving trough and lower tooth receiving trough which are separated at an anterior end and connect at a posterior end by a resilient hinge which biases the appliance into an open position with the two trough anterior ends urged apart. Such an appliance can be manufactured by slitting the appliance after molding, before it has cooled, to thermoset the hinge in an open position or by molding the appliance in an open position. The hinge is integrally molded into the appliance (the '535 patent, column 3, lines 29 to 36), preventing removal of the hinge from the device and separation of the upper trough from the lower trough.

Nowhere does the '535 patent disclose that the hinge is removed and re-inserted into the first slot and the second slot to reversibly detach and re-attach the upper base to the lower base as required by amended Claim 21. Further, nowhere does the '535 patent disclose that the hinge has an upper portion and a lower portion wherein the upper base has a first slot and a second slot wherein the upper portion of the hinge is removed and re-inserted into the first slot and lower portion of the hinge is removed and re-inserted into the second slot to reversibly detach and re-attach the upper base to the lower base as required by amended Claim 47. Moreover, nowhere does the '535 patent disclose that returning the hinge to the upper slot in the upper base and the lower slot in the lower base re-attaches the upper base to the lower base as required by amended Claim 112.

Under 35 U.S.C. §102(b), anticipation requires that a single reference discloses each and every element of Applicant's claimed invention. *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1479, 1 USPQ 2d. 1241, 1245 (Fed. Cir. 1986). Moreover, anticipation is not shown even if the differences between the claims and the reference are "insubstantial", and one skilled in the art could supply the missing elements. *Structure Rubber Products Co. v. Park Rubber Co.*, 749 F.2d. 707, 716, 223 USPQ 1264, 1270 (Fed. Cir. 1984).

Since the '535 patent fails to disclose a dental appliance as defined in independent Claims 21, 47 and 112, Applicant asserts that

the rejection of Claims 21, 47, 49, 52-55 and 112 under 35 U.S.C. §102(b) has been overcome and should be withdrawn.

With respect to the rejection of Claims 50 and 51 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of the '199 patent, Applicant submits that the rejection has been overcome in view of the foregoing amendments and the remarks that follow.

The '199 patent merely teaches an orthodontic appliance for assisting in properly positioning teeth within the mouth of an individual which has a labial-buccal flange, a lingual flange spaced from the labial-buccal flange, both of which define a generally U-shaped configuration in the occlusal view, and an isthmus interconnecting the two flanges. The appliance has no individual tooth sockets but instead utilizes pressure applied by the labial-buccal flange, the lingual flange, and relative angles and material thicknesses to properly position the teeth. The appliance is capable of fitting mouths and teeth of various sizes because it includes no individual tooth sockets. The hinge is integrally molded into the appliance.

Neither the '535 patent nor the '199 patent, taken singly or in combination, teaches or suggests that the hinge has an upper portion and a lower portion wherein the upper base has a first slot and a second slot wherein the upper portion of the hinge is removed and re-inserted into the first slot and lower portion of the hinge is removed and re-inserted into the second slot to reversibly detach

and re-attach the upper base to the lower base as required by amended Claim 47, from which Claims 50 and 51 depend. Since the '199 patent fails to teach or to suggest the elements of the present invention which are not taught by the '535 patent, as required by amended independent Claim 47 from which Claims 50 and 51 depend, Applicant asserts that the rejection of Claims 50 and 51 under 35 U.S.C. §103(a) has been overcome and should be withdrawn.

For the 35 U.S.C. §103(a) rejection of Claims 50 and 51 as being unpatentable over the '535 patent in view of the '199 patent, the question is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in the art. *In re Simon*, 461 F. 2d 1387, 174 USPQ 114 (CCPA 1972). That elements, even distinguishing elements, are disclosed in the prior art is insufficient. It is common to find elements somewhere in the art. The test is whether the invention as a whole, in light of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 722 F. 2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

With the analysis of the lacking elements in the '535 patent and the '199 patent in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to combine the '535 patent with the '199 patent to produce the claimed inventions for better treating malocclusions. The mere disclosure of distinguishing

elements in the prior art is insufficient. *Connell*, 722 F. 2d 1542. Furthermore, when combining two references, a teaching or suggestion must exist to make the combination made by Applicant. *Interconnect Planning Corp. V. Feil*, 774 F. 2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1988). With the analysis of the lacking elements in the '535 patent and the '199 patent in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to combine the references to produce the claimed invention. Therefore, *prima facie* obviousness has not been established as required under 35 U.S.C. §103(a).

Moreover, combination of the references still does not provide that the hinge has an upper portion and a lower portion wherein the upper base has a first slot and a second slot wherein the upper portion of the hinge is removed and re-inserted into the first slot and lower portion of the hinge is removed and re-inserted into the second slot to reversibly detach and re-attach the upper base to the lower base as required by amended Claim 47, from which Claims 50 and 51 depend. The rejection of Claims 50 and 51 under 35 U.S.C. §103(a) as being unpatentable over '535 patent in view of the '199 patent should be withdrawn.

With respect to the rejection of Claim 52 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of the '420 patent, Applicant submits that the rejection has been overcome in view of the foregoing amendments and the remarks that follow.

The '420 patent merely discloses tooth receiving troughs which have a plurality of depressions to receive teeth. While the '420 patent does reference a "hinge", the "hinge" is an integral injection molded hinge continuous in material with the upper and lower troughs, as shown by the disclosed method of making the appliance by slitting one piece of material along a central line, described in column 4, line 57 to column 5, line 18, and depicted in Fig. 15. A removable hinge member that makes the shells of the device separable in their entirety and allows for subsequent re-attachment is an structural distinction from a device with a hinge integrally formed within the device where the injection molded hinge connects the shells inseparably.

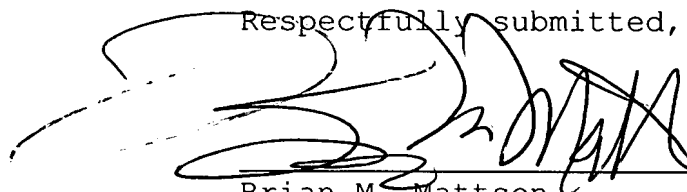
Neither the '535 patent nor the '420 patent, taken singly or in combination, teaches or suggests that the hinge has an upper portion and a lower portion wherein the upper base has a first slot and a second slot wherein the upper portion of the hinge is removed and re-inserted into the first slot and lower portion of the hinge is removed and re-inserted into the second slot to reversibly detach and re-attach the upper base to the lower base as required by amended Claim 47, from which Claim 52 depends. Further, with the analysis of the lacking elements in the '535 patent and the '420 patent in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to combine the references to produce the claimed invention. Therefore, *prima facie* obviousness has not been

established as required under 35 U.S.C. §103(a). The rejection of Claim 52 under 35 U.S.C. §103(a) as being unpatentable over '535 patent in view of the '420 patent should be withdrawn.

Claims 49-52 depend from independent Claim 47. These claims are further believed allowable over the references of record for the same reasons set forth with respect to their parent claims since each sets forth additional novel features of Applicant's dental appliance.

In view of the foregoing remarks and amendments, Applicant respectfully submits that all of the claims in the application are in allowable form and that the application is in condition for allowance. If, however, any outstanding issues remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

Respectfully submitted,



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I hereby certify that this **Amendment, Amendment Transmittal (in duplicate)** and **Return Receipt Postcard** are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 14, 2007.

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